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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,016	10/02/2000	Keith P. Wilson	VPI/96-03 DIV2	7947

1473 7590 05/28/2002  
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EXAMINER
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GALITSKY, NIKOLAI M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/678,016

Applicant(s)

WILSON ET AL.

Examiner

Nikolai M. Galitsky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23-25 and 27-36 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23 and 27-36 is/are rejected.
- 7) ☒ Claim(s) 23 and 27-36 is/are objected to.
- 8) ☒ Claim(s) 23-25 and 27-36 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Pages 4 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

#### **RESPONSE TO RESTRICTION REQUIREMENT:**

Applicants' elections with traverse of Group IV, in Paper Nos. 3, filed March 18, 2002, is acknowledged. The traversal is on the ground(s) that there is no serious burden for the Examiner to search the claims of both Groups IV and V because these searches overlap extensively. This is not found persuasive because the restriction Groups are patentably distinct over each other due to the different subject matter from Group to Group. For instance, Group IV is directed to ligand binding modeling to whatever three dimensional structure is desired, whereas Group V is directed to the practice a method of utilizing molecular replacement, which includes the methods of crystallization, generating an x-ray diffraction pattern from said crystallized molecule, a structure solution, and etc. Thus, the different subject matter of Group IV and V clearly document the undue search burden if those Groups were searched together, contrary to the to the allegations of applicants. The basis for separation restriction grouping clearly was previously set forth as differences in the methods as summarized above. Applicants' traversed argument is not directed to this basis for restriction and therefore moot. Also, each class/subclass such as 702/19 encompasses a multitude of inventions.

The requirement is still deemed proper and is therefore made FINAL.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title includes more than the claimed methods, such as evaluating the ability of a chemical entity and structure of a binding pocket.

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If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression “now Patent No.6,128,582” should follow the filing date of the parent application. If a parent application has become abandoned, the expression “now abandoned” should follow the filing date of the parent application.

Claims herein under examination are claim 23 and 27-36.

*Claim Rejections - 35 USC § 101 and §112*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23 and 27-36 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to a process (method of evaluation); however, claims 23 and 27-36 recite only steps of computation and analysis.

As set forth in MPEP 2106, “The claimed invention as a whole must produce a “useful, concrete and tangible” result to have a practical application. A process that consists solely of the manipulation of an abstract idea is not concrete or tangible. See *In re Warmerdam*, 33 F.3d 1354, 1360, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). See also *Schrader*, 22 F.3d at 295, 30 USPQ2d at 1459”, and “... a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process. In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application

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(i.e., executing a “mathematical algorithm”); or – simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application. “

The computation and analysis steps of claims 23, and 27-36 are mathematical operations, and the claims do not recite any concrete or tangible results, therefore the claims do not recite statutory subject matter.

As set forth in MPEP 2106 IV.B.2 (b) (ii):

Examples of claimed processes that do **not** achieve a practical application include:

- step of “updating alarm limits” found to constitute changing the number value of a variable to represent the result of the calculation (Parker v. Flook, 437 U.S. 584, 585, 198 USPQ 193, 195 (1978));
- final step of “equating” the process outputs to the values of the last set of process inputs found to constitute storing the result of calculations (In re Gelnovatch, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979); and
- step of “transmitting electrical signals representing” the result of calculations (In re De Castelet, 562 F.2d 1236, 1244, 195 USPQ 439, 446 (CCPA 1977) (“**That the computer is instructed to transmit electrical signals, representing the results of its calculations, does not constitute the type of post solution activity’ found in Flook, [437 U.S. 584, 198 USPQ 193 (1978)], and does not transform the claim into one for a process merely using an algorithm. The final transmitting step constitutes nothing more than reading out the result of the calculations.”**)); and
- step of displaying a calculation as a gray code scale (In re Abele, 684 F.2d 902, 908, 214 USPQ 682, 687 (CCPA 1982)). Emphasis added by examiner.

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As previously set forth and reiterated above, the claimed methods do not, in themselves, produce a useful, concrete, and tangible results. For examples of “computer-related” methods which recite manipulation of data AND which produce a concrete, tangible, and useful result, applicant’s attention is directed State Street (47 USPQ2d 1596 at 1601), wherein the method claimed was held to be statutory because the transformation of data recited in the claims resulted in a final share price, which was held to be a concrete, tangible and useful result. Similarly, the decision in Alappat (31 USPQ2d at 1557) held a smooth waveform produced by transformation of data was a useful, concrete, and tangible result. In contrast, the instant claims recite a method “for evaluating” wherein a “fitting operation” is performed by “computational means”, and the results are “analyzed” quantitatively. The instant claims do not recite any specific result, nor any actual transformation of data, which would produce a result that is concrete, tangible, and useful. Evaluation and analysis are not steps of transforming data. A “valuating ability”, as taught by the instant specification, appears to be one of either “matching” or “docking” a three-dimensional model of a chemical entity to a binding pocket, akin to fitting puzzle pieces together; or appears to be one of energy minimization (e.g. as set forth on pages 20-21). Neither appears to be a transformation of data which provides a useful, concrete, and tangible result.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

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"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 23 and 27-36 rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed chemical entity or compound (see specification on page 11, lines 15-16 and line 32) is not supported by a specific asserted utility because the disclosed uses of these

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compositions are not specific and are generally applicable to any compounds. These are non-specific uses that are applicable to compound(s) and/or proteins in general being claimed.

Further, the claimed chemical entity, or compound, or portion thereof is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a compound may be utilized to obtain a protein complex. The protein complex could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function are not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the compounds that are to be produced as final products resulting from processes involving claimed 3-D structure of IMPDH have asserted or identified specific and substantial utilities. The research contemplated by applicant(s) to characterize potential compound products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the therapeutic chemical entity such that another non-asserted utility would be well established for the compounds.



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The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 and 27-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

*Rejection Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 27-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 (line 1) the “evaluating the ability” implies that the ability is chosen by some kind of criteria. Applicant can resolve this issue by particularly pointing out what type of the evaluation relating to the ability of a chemical entities are chosen. The implied criterion is critical in applying to a method for evaluating the ability of a chemical entity, and therefore it is unclear.

Claim 29 (line 1) the “evaluating the ability” implies that the ability is chosen by some kind of criteria. Applicant can resolve this issue by particularly pointing out what type of the evaluation relating to the ability of a chemical entities are chosen. The implied criterion is critical in applying to a method for evaluating the ability of a chemical entity, and therefore it is unclear.

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Claim 23(b) (line 1) the “quantify of the association” implies that the determined quantity is chosen by some kind of criteria. Applicant can resolve this issue by particularly pointing out what kind of criteria for quantity relating to the ability of a chemical entity to associate with a molecule or molecular complex, is chosen. The implied criterion is critical in applying to a method for evaluating the ability of a chemical entity, and therefore it is unclear.

Claim 29(b) (line 1) the “quantify of the association” implies that the determined quantity is chosen by some kind of criteria. Applicant can resolve this issue by particularly pointing out what kind of criteria for quantity relating to the ability of a chemical entity to associate with a molecule or molecular complex, is chosen. The implied criterion is critical in applying to a method for evaluating the ability of a chemical entity, and therefore it is unclear.

Claim 23(a), line 1 is cited “computational means” without any means determination whatsoever, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 29(a), line 1 is cited “computational means” without any means determination whatsoever, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 23 and 27-36 are rejected to because of the abbreviations such as IMPDH, XMP\*, and MPA make the claims vague and indefinite. Applicants should provide the full name.

The disclosure is objected to because of the following informalities:

Claims 23 and 29 contain improper periods within the claims. For example, claim 23 contains improper periods in the designations for the steps, such as "a." and "b.". Applicants may replace, for example, "a." by "a)" or "(a)".

Appropriate correction is required

No Claims Are Allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai M Galitsky, Ph.D., whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Williams Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 24, 2002  
NG

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER